

## EXHIBIT 391

**PURDUE**

SUBJECT:	ORDER MANAGEMENT SYSTEM
SOP NO.:	GC-SOP-0007
COVERAGE:	General Counsel, National Accounts, Corporate Security, CSA Compliance
EFFECTIVE DATE:	March 23, 2009
SUPERSEDES:	ALL PREVIOUS COMMUNIQUE
REFERENCE:	NONE

**PURPOSE**

The purpose of this SOP is to describe Purdue's efforts to comply with the Drug Enforcement Administration's ("DEA") rules and regulations and enhance our systems, review and vigilance in the area of suspicious order monitoring. As part of this initiative, Purdue has developed an Order Monitoring System ("OMS") described in this SOP to create a detailed and appropriate assessment process of selected accounts, including its authorized distributor customers and some of their retail customers. The assessments will be utilized to consider the need for follow up action and to support our authorized distributors in their own order monitoring programs and in their efforts to "know their customers".

**BACKGROUND AND RISK**

Purdue markets medications that are scheduled under the Controlled Substances Act, which are by definition subject to potential abuse and diversion. As a DEA registrant, Purdue is charged with maintaining effective controls against diversion of controlled substances into other than legitimate medical, scientific, and industrial channels. This includes reasonable efforts to "know our customers" as well as aiding in the efforts of our distributors to ensure that they take reasonable steps to "know their customers".

We recognize our obligation to support DEA's mission to prevent the diversion of controlled substances from legitimate sources while ensuring an adequate and uninterrupted supply of our products for legitimate medical and scientific purposes. As part of this SOP, we seek to fulfill our responsibility as a manufacturer and a distributor to conduct independent analysis and exercise due diligence to avoid filling suspicious orders that might be diverted into other than legitimate medical, scientific and industrial channels. §21 USC 823(e). We recognize as a manufacturer and a distributor we may not simply rely on the fact that the person placing the order is a DEA registrant and fail to scrutinize what may be suspicious circumstances. Rather we must exercise due care in confirming the legitimacy of all orders prior to filling.

We recognize that pertinent regulations require that registrants inform the local DEA Field Division Office of suspicious orders when discovered by the registrant (21 CFR § 1301.74(b). Registrants must separately evaluate whether it is appropriate to fill an order regardless of whether notification has been made to law enforcement (DEA correspondence).

Furthermore, we are aware that DEA has taken the position that failure to implement and follow appropriate suspicious order monitoring procedures may result in the revocation of the

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registrant's DEA Certificate of Registration. §21 USC 823 and 824. The suspension or revocation of a registration shall operate to suspend or revoke any quota applicable under section 826 of this title.

DEA action may extend to entities that illegally distribute controlled substances through traditional means is not limited to the internet. Purdue recognizes that it must exercise due care and diligence to ensure that it takes all appropriate steps to ensure that it is not filling orders to distributors about whom Purdue has developed credible evidence of diversion or sales to illicit sources.

**ORDER MANAGEMENT SYSTEM ("OMS") REVIEW**

As part of this SOP, Purdue has instituted and developed an OMS program to review data received from Purdue's authorized distributors per fee for service (FFS data)<sup>1</sup> contracts. The program uses certain specified parameters to determine which accounts, wholesaler or retail, shall be subject to further review in an effort to ascertain whether any order or series of orders meets the standard of being "suspect" and warrant a potential DEA referral.

An account will be reviewed as part of the OMS program if the FFS data entered falls outside established parameters based upon certain norms, or other indicia are present that suggest further review is appropriate. This process is updated on a monthly basis as new data is received.

The criteria are based on looking at the population of retail customer data received via FFS and identifying outliers based on statistical analysis (i.e. based on average and standard deviation of comparable customer populations).

The factors considered at present (subject to modification as needed or based upon experience gained through this program) include:

- a. Number of wholesalers from which retail account purchases,
- b. Number of times retail account orders the same product the same day,
- c. Percentage of order including Purdue products other than Oxycontin,
- d. Total dollar value of Oxycontin and
- e. Percentage of 80mg strength being purchased.

<sup>1</sup> FFS data covers approximately 93% of Purdue's product distribution. The remaining 7% is assessed by means of different methods by the team and discussions are held with the authorized "secondary" distributors as needed.

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Follow up review of accounts identified by the OMS is conducted by an inter-disciplinary group, including representatives from the Office of the General Counsel, CSA Compliance, National Accounts and Corporate Security. Follow up may include a discussion with the authorized distributor. If a referral is to be made to the Drug Enforcement Administration ("DEA"), that will be handled by CSA Compliance.

For accounts selected by the system under the current criteria (notify distributor(s) if it's a retail acct), the OMS team review will proceed as follows:

All Pharmacies will be assigned to "National Accounts" for initial feedback based upon familiarity with account, comparison with similar accounts, or other information or context for particular order.

When National Accounts review is complete, CSA Compliance acting on behalf of the Office of the General Counsel, will review available information and provide feedback and suggestions, which may include a request for further information from Sales relative to other pharmacy or healthcare practitioners in the vicinity of subject account.

The pertinent field representative and his or her supervisor will be notified when a retail account requires further scrutiny from a local representative with a request to provide certain information.

After the Sales Force responds, the responsive information will be added to the database. The file will be further reviewed by Corporate Security for any additional relevant information that may be available.

Following Corporate Security Review it may be marked for CSA Compliance Review, which will generally take place in conjunction with the other reviewers as a summary discussion.

The reviewing team, under the guidance and direction of the General Counsel's Office will then discuss and perform next steps, as appropriate and coordinate its assessment with the authorized distributor.

The OMS system has the capability to be searched by Name, City, State or Zip code. The reviewing group are expected to perform individual due diligence prior to quarterly OMS meetings. All pharmacies that have notes in the system can be pulled up and studied by any member of the OMS team after review of the relevant data has been completed by participating OMS team members. Some coordinated activity will take place as needed, and information will

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be provided and updated on a periodic basis. Notes of activities will be maintained by CSA Compliance on behalf of the General Counsel's Office.

There are 3 final status values for all pharmacies that were identified for follow up review:

Pending, action; This indicates that the team has completed its initial due diligence, and feels that further inquiries must be made in order to properly assess the account and/or coordination with the authorized distributor must be scheduled.

Complete, closed; This indicates that the team took an action or it was concluded by the team that the account was not a concern based on available information - no further review at this time.

Complete, referred; This indicates that it was determined that there was sufficient information that indicated a potential suspicious order, thus requiring referral to the local DEA Field Division Office. If a referral is made, Purdue will notify its authorized distributor of such action.

### **FILING SUSPICIOUS ORDER REPORTS WITH DEA**

#### **a. Immediate DEA Notification**

Under 21 C.F.R. § 1301.74(b), orders designated as "suspicious" must be reported to DEA "when discovered." Once the determination that an order is suspicious has been made, a phone call to report the order to the local DEA office is recommended to meet this requirement (unless DEA provides other direction). If requested, Purdue will provide additional information.

- Even if there is some ambiguity regarding a customer or an order's status, occasions may arise when the intended use of an order is questionable. For example, the distributor may identify information that leads them to believe that a potential customer, prior to entering a formal business arrangement with that customer, may intend to order controlled substance products with a frequency, volume or other indicator that could be considered "suspicious." In such instances, the distributor should provide DEA with a report of this information under 21 C.F.R. § 1301.74(b).
- Distributors are strongly encouraged to regard timeliness of reporting to DEA as a critical component in meeting the requirement to report "when discovered."

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**b. Correspondence for Reporting**

It is recommended that all correspondence to DEA (containing reports of suspicious orders) should be sent registered mail with a return receipt requested, by electronic mail or by another system that creates for the distributor a permanent record that DEA has received the notification. Written correspondence to the local DEA office is encouraged as a follow-up to a telephonic notification.

Reports will follow this format: "This report is submitted to you in accordance with the requirements of 21 C.F.R. § 1301.74(b) and is for (company name)." When the return receipt is received, it should be stapled to the cover letter as proof of submittal.

In some states, additional reporting requirements may apply. Purdue will determine whether a state report is required, and comply accordingly.

It is recommended that the same person conduct the investigation, decide (in consultation with one or more colleagues and/or managers) whether or not to cancel the order, and also provide the report to DEA.

**c. Documentation**

All contact with DEA, either by telephone or in person, should be documented; and a record of the contact should be maintained.

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